

1 **Sustained release formulations containing acetaminophen and tramadol**

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6 **Abstract**

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8 A sustained release formulation as a unit dose contains 100 mg – 1000 mg of
9 Acetaminophen and 15 mg – 150 mg of tramadol hydrochloride, which comprises of 1)
10 an immediate release portion comprising of 25% - 75% of the total effective amount of
11 drug in the dosage form and 2) a sustained release portion comprising of a) 25% - 75%
12 of the total effective amount of drugs in the dosage form; b) 6% - 50% of gelling
13 polymers of the total formulation, and c) optionally an enteric coating at a level of 5% -
14 40% of the total formulation. The set forth formulation dissolves 25% - 60% of the total
15 drug in the first hour, 50% - 90% of the total drug in the first four hours and not less than
16 80% of the total drug in the first 12 hours using USP dissolution method II at 50 rpm.

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18 ***Description***

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20 **FIELD OF THE INVENTION**

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22 The present invention is directed to a sustained release formulation of Acetaminophen
23 and tramadol. Particularly, this invention is related to a formulation and dissolution
24 specifications from a sustained release dosage form of acetaminophen tramadol in
25 connection with an improved dose segment for a better patient compliance.

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